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University of Dundee

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Manuscript Title: Art participation for psychosocial wellbeing during stroke rehabilitation: a feasibility randomised controlled trial.

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35

36 **Trial Registration:**

37 Registry: Clinical Trials.gov

38 Date of Registration: 6th March 2014

39 Date of first participant enrollment: July 2013

40 Registration Number: NCT 02085226

41 URL: <https://clinicaltrials.gov/ct2/show/NCT02085226?term=NCT02085226&rank=1>

42 Registration was late because we had not been informed by our clinical trials unit of the
43 need to register before the start of recruitment. We registered the trial as soon as we
44 knew that we should. We have full details of our ethics protocol that provides evidence
45 of our trial history.

46

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48

49 **Tables**

50 table 1. Intervention Stages

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54 effect size estimation at T2

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56 effect size estimation at T3

57 figure 1. Participant flow through the study

58

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Purpose: To examine the feasibility of undertaking a pragmatic single-blind randomised controlled trial of a visual arts participation programme to evaluate effects on survivor wellbeing within stroke rehabilitation.

Methods: Stroke survivors receiving in-patient rehabilitation were randomised to receive eight art participation sessions (n=41) or usual care (n=40). Recruitment, retention, preference for art participation and change in selected outcomes were evaluated at end of intervention outcome assessment and three-month follow-up.

Results: Of 315 potentially eligible participants 81 (29%) were recruited. 88% (n=71) completed outcome and 77% (n=62) follow-up assessments. Of eight intervention group non-completers, six had no preference for art participation. Outcome completion varied between 97% and 77%. Running groups was difficult because of randomisation timing. Effectiveness cannot be determined from this feasibility study but effects sizes suggested art participation may benefit emotional wellbeing, measured on the Positive and Negative Affect Schedule, and Self-efficacy for Art (d=0.24-0.42).

Conclusions: Undertaking a randomised controlled trial of art participation within stroke rehabilitation was feasible. Art participation may enhance self-efficacy and positively influence emotional wellbeing. These should be outcomes in a future definitive trial. A cluster randomised controlled trial would ensure art groups could be reliably convened. Fewer measures, and better retention strategies are required.

Key words: Stroke Rehabilitation, Art, Emotions, Affect, Wellbeing

Introduction

Stroke is the main cause of complex adult disability. Annually 16 million people worldwide experience stroke¹ of whom 85% experience motor, cognitive or communication impairments². These limit independence in activities of daily living (ADL) and restrict participation in life roles². Around 31% of survivors experience post-stroke depression within five years post-stroke³. Along with physical impairments, the psychological consequences of stroke include depression, and lower optimism, self-esteem and perceived control. These consequences are associated with poorer wellbeing and quality of life⁴.

Wellbeing is viewed as balance between physical, psychological and social resources, and challenges to those resources⁵. Stroke presents a challenge to the balance, causing sudden and unexpected threats to resources that negatively influence wellbeing. Kirkevold^{6,7} suggests wellbeing after stroke depends on positive emotion, engagement in meaningful activities, good social relations, self-esteem and belief in one's own abilities. Finding ways to improve wellbeing after stroke within rehabilitation by addressing these factors is therefore a logical avenue for exploration.

The benefits of participating in meaningful leisure activities to address wellbeing after stroke, are becoming recognised⁸. The importance of arts in healthcare is reflected in international healthcare policy documents^{9,10}. Models of psychological care after stroke¹¹ suggest activities including art participation within stroke rehabilitation, may enhance wellbeing, preventing escalation to more serious psychological problems. Arts programmes led by professional artists focus on benefits to wellbeing through artwork creation, by enabling people to realise their creative potential. Programmes are open to all survivors and are not psychotherapeutic art therapy for specific psychological problems. Despite recent endorsement of art participation in healthcare models and

policy, research evidence supporting benefits of art participation on wellbeing after stroke is scant.

Two qualitative studies^{12,13}, respectively involving sixteen and six survivors who received in-patient stroke rehabilitation suggest that wellbeing, rehabilitation goal achievement and renewed identity are benefits of arts participation. Two others^{14,15}, respectively involving 20 and 24 community dwelling stroke survivors, suggest art participation may enhance self-esteem, self-efficacy and confidence. Despite these positive reports, the diverse range of potential benefits means that defining measures for evaluation of effects of art participation is challenging. Only one previous randomised controlled trial (RCT) of art participation within stroke rehabilitation was found, involving 118 in-patient stroke survivors¹⁶. The study demonstrated improved depression, quality of life and cognition, compared to usual care, following visual art-making combined with meditation and singing. However, it is unclear how each intervention component contributed to effects, therefore specifically evaluating effects of artmaking in its own right is warranted.

A person-centred arts participation programme developed collaboratively with artists, academics and stroke survivors has been routinely delivered within a Scottish health board. A qualitative study with three artists who delivered that programme, and eleven previous participants¹⁷ showed the programme enhanced perceptions of hope, self-efficacy and perceived control over recovery as central components of enhanced wellbeing. Other benefits included physical and communication recovery, self-esteem and positive emotional state. These benefits were operationalised using standardised outcome measures congruent with models of wellbeing, as described within the intervention model identified in preliminary work to model the intervention¹⁷. The qualitative work facilitated modelling of the existing intervention into a protocol for use in an RCT, which was tested in a feasibility RCT.

Feasibility trials examine key trial parameters, such as intervention feasibility, recruitment, loss to follow-up, completion and relevance of outcome measures, to optimise a subsequent definitive RCT. They also evaluate if proceeding to a definitive trial is appropriate¹⁸. Undertaking a feasibility trial of art participation is critical to inform a future definitive trial, since so few RCTs exist.

The present study aimed to examine feasibility of conducting a future definitive RCT of the art participation programme within in-patient stroke rehabilitation. It aimed to examine participant recruitment and retention rates, and because art participation may have limited appeal, to examine if preference for art participation influenced retention. A further aim was to examine the appropriateness of the selected primary outcome measure and other measures, and to explore magnitude and direction of change to determine if progress to a definitive RCT was warranted.

Design

This pragmatic single-blind feasibility randomised controlled trial was informed by the Medical Research Council Framework for Complex Intervention Development¹⁹. The published study protocol provides in-depth methodological details²⁰. A brief description is provided below.

Methods

East of Scotland Research Ethics Service provided approval: ref. no. 13/ES/0006. Clinicaltrials.gov. Registration number: NCT02085226.

Participants and setting

People diagnosed with stroke admitted to two stroke rehabilitation units in North East Scotland were screened for trial inclusion within one week of admission to rehabilitation, typically less than two weeks after stroke onset. Two study researchers, the research

manager, also an artist, researcher and co-author – and a psychologist conducted screening and obtained informed consent for participation from interested stroke survivors.

Medically stable survivors participating in usual rehabilitation therapies and with planned rehabilitation duration of at least three weeks were considered eligible. People diagnosed with transient ischaemic attack; who were unconscious; medically unwell; unable to participate in usual rehabilitation activities or to provide informed consent, were excluded.

Sample size calculation

Formal sample size calculation was not conducted, as this was a feasibility RCT. The sample size, of 40 participants per group, was based on guidance that a sample of that size was adequate to provide fairly accurate estimates of direction and magnitude of effects and variability²¹.

Randomisation

Randomisation to intervention or control was conducted after baseline assessment using secure, remote, web-based, concealed computer-generated randomisation. Minimisation was applied to ensure that groups were balanced. To minimise the effects of recruiting from two centres stroke unit was included as a minimising factor as well as age (≤ 60 years, 61-80 years, ≥ 81 years), gender, and likelihood of independence in activities of daily living, according to Barthel Index scores²², grouped as scores of 0-40, 45-55, 60-100²³.

Intervention Group

Participants randomised to the intervention group received the modelled visual arts participation programme in addition to usual rehabilitation. Two qualified visual artists,

with five and seven years of experience respectively of working in healthcare settings, delivered the art participation programme. The research manager, an experienced artist and researcher, trained the artists and assessed their performance of trial procedures, delivery of intervention stages, goal setting with participants, and progress review, prior to study commencement. Planned intervention delivery involved one session per week with the artist and one group session with other participants, to a maximum of eight sessions, because of known benefits of each approach^{12,14,24}. Individual sessions lasted one hour and group sessions one hour and thirty minutes. Usual rehabilitation typically involved physiotherapy, occupational therapy, and as necessary, speech and language therapy. One half hour session was delivered by each therapy on most weekdays.

The art participation programme was targeted at individual survivors and included three components identified as central mechanisms of action¹⁷: *Social Context* for art participation - the social setting of the group or individual sessions with the artist; *Art-making Processes* - art-making itself, individually tailored to participants' needs and interests and *Creative Output* – the finished product. Art-making involved five carefully defined stages, allowing intervention replication, whilst facilitating tailoring of activities and materials to participants' interests and abilities. Participants could repeat stages several times, depending on progress. Full intervention details according to TIDIER guidelines²⁵ are reported elsewhere²⁰. Intervention Stages are provided in Table 1.

Insert Table 1 about here

Control Group

Control participants received usual stroke rehabilitation. To maintain participants' interest in the study and reflect usual practice within those units, after baseline assessment and randomisation, a portfolio of work produced by previous participants of

the existing programme was provided to the control group. No specific instruction was given, other than informing them that it had been produced by other stroke survivors. At final outcome assessment, study researchers discussed options for participation in community art programmes.

Measures and measurement instruments

Measures at baseline included age, gender, stroke type (ischaemic/haemorrhagic) and side of hemiplegia, as well as the Barthel Index²²; Montreal Cognitive Assessment²⁶; NIH Stroke Scale²⁷; Edinburgh Handedness Inventory²⁸; Communication: Aphasia Severity Rating Scale²⁹

Qualitative work to inform this study suggested art participation may foster positive resources that contribute to wellbeing, and guided outcome selection. Consultation with stroke survivors led to the final choice of outcome measures. Detailed scoring and psychometric properties are described in the trial protocol, and only brief detail is provided here³⁰.

The Stroke Impact Scale questionnaire³¹ was selected as a potential primary outcome measure, as it measures specific domains of stroke related quality of life³². Emotion, Hand Function, Communication and Social Participation were examined, given those domains were relevant from the earlier qualitative work^{17,20}. Items are rated on a five-point Likert scale indicating difficulty completing the item. Summative scores for domains range from 0 to 100.

The potential secondary outcome measures examined positive emotional wellbeing rather than absence or presence of clinical disorders such as anxiety and depression. The Positive and Negative Affect Schedule³³ measured emotional wellbeing. The focus on

positive affect reflects the selected definition of emotional wellbeing and the potential impact of art identified from previous literature. Positive affect represents pleasurable engagement and includes emotions such as enthusiasm and alertness. Negative affect is characterised by subjective distress and un-pleasurable engagement. Items are scored on a five-point scale [1-5], higher scores indicate higher emotion. Total scores range from 10 to 50.

This study and others indicated that art participation may enhance self-esteem¹⁴. The Visual Analogue Self-esteem Scale³⁴ was developed for people with aphasia, and was accessible to study participants. Visually represented constructs are rated on a scale of 1-5. Item responses are summed providing a total score between 10 and 50.

Perception of control over recovery was indicated in the qualitative work to inform this study as a positive benefit of art participation¹⁷. The stroke specific Recovery Locus of Control Scale assessed this domain³⁵. It is a nine-item scale measuring internal and external control beliefs relating to recovery. Degree of control is rated between 1 and 5. Summed items indicate strength of internal control, with 9 indicating minimum and 45 maximum.

Hope predicts recovery after stroke³⁶. The Trait Hope Scale reflects hope of achieving broader life goals, an outcome that was attributed to art participation in previous research¹⁷. It is a 12-item measure with four item Lickert subscales of agency and pathway. Pathway focuses on routes to achievement of goals; and agency focuses on motivation and confidence to achieve them. The domains of the measure captured mechanisms through which art participation might provide hope.

Art making appeared to develop confidence to achieve art-specific goal achievement *and* personal rehabilitation goals^{14,17}. To capture this general confidence, the General Self-Efficacy Scale³⁷ was selected, a 10-item scale assessing confidence to deal with life demands. Responses are scored 1-4 and summed to a total of 40, indicating maximum self-efficacy. The scale is widely used with stroke populations.

Self-efficacy for art was assessed by two single item questions, using an established procedure³⁸. The questions are: 1. How confident are you that you can express yourself through art activities? 2. How difficult do you find it to express yourself through art activities? Self-efficacy for art expression is scored on a seven-point vertical visual analogue scale with one as least confident/difficult and seven as most confident/difficult.

Because art participation may not appeal to all, preference for randomisation to doing or viewing art, or no preference, was assessed using a simple question after randomisation.

Number of eligible participants, recruitment, retention, preference for art participation and follow-up rates were also collected.

Trial Procedures

As per local ethical regulations, nursing and rehabilitation staff identified potential participants and provided them with study information. Those expressing interest were screened by the research team to ensure they met inclusion criteria, and written informed consent for participation was obtained. Baseline measures at time one (T1) were collected and participant details entered into a secure, remote, web-based randomisation system by the study researchers, after which artists were informed of group allocation. The system was accessed by a password known only to the study team.

304

305 An assessor trained in measures and blind to group allocation conducted outcome
306 assessments at time two (T2) and follow-up assessments at time three (T3). Intervention
307 group T2 assessment was conducted at four weeks after eight art sessions - two per week
308 - had been completed, or at hospital discharge if discharge occurred before eight sessions
309 had been completed. Control group T2 outcomes were also assessed at four weeks, or
310 discharge if sooner. Participants were instructed not to reveal group allocation to the
311 assessor. T3 assessment was undertaken three months after T2 assessment in hospital or
312 participants' homes depending on discharge status.

313

314 ***Data analysis***

315 Proportions of survivors who were eligible for participation, who provided consent to
316 participate, who withdrew and who had different preferences for art participation were
317 assessed. Within-group change and between-group differences were examined to inform
318 primary outcome measure selection for a definitive RCT. Evaluation of treatment
319 effectiveness was not the purpose of this study, so statistical analysis was kept to a
320 minimum. Data were screened for normality and transformed where required. Data for
321 continuous outcome measures were assessed for normality prior to analysis. Where data
322 was found to be non-normally distributed, right-skewed data were transformed by
323 logarithm (base e) to achieve a normal distribution, while left-skewed data was
324 transformed by squaring. Where transformation led to a normal distribution, the
325 transformed data were analysed as a sensitivity analysis to confirm the original analysis.

326

327 Data were summarised and changes from baseline calculated. To assess variability,
328 magnitude and direction of mean between group difference at T2 and T3 was conducted
329 using analysis of covariance, adjusting for baseline co-variates, and 95% confidence
330 intervals for the difference were recorded. Cohen's d effect size was calculated by dividing

group means at T2 and T3 by the pooled standard deviation. The statistician undertaking analysis was blinded to group status until after the main analysis was conducted. Data were stored in accordance with the UK Data Protection Act 1998³⁹.

Results

Recruitment

Over 12 months, 284 stroke survivors admitted to rehabilitation units for eligibility were screened. Of those, 117 (41%) were eligible, but chose not to participate. 86 (30%) were not eligible for a range of medical reasons. 81 (29%) provided informed consent for participation. 41 were randomised to receive the intervention, 40 to the control group. Reasons for exclusion are reported in figure 1, and participant characteristics are presented in Table 2.

Insert figure 1 about here

Insert table 2 about here

Retention

Eight intervention (20%) and two control participants (5%) withdrew before T2. Six of those withdrawing from the intervention group expressed no preference, or preferred the control option of art viewing. Although numbers were insufficient for statistical testing, baseline primary outcome measure scores for intervention group dropouts were higher at T1 (n=8) compared to T2 completers (table 3), suggesting dropouts might differ in some ways from those remaining in the study.

Insert table 3 about here

At T3 three further intervention group participants and six control participants could not be contacted, leaving the intervention group completion rate of 73% (n=30/41) and control group of 80% (n=32/40).

The number of art sessions (Mean, Standard Deviation) received by the intervention group was 5.7 ± 2.5 . However, frequently only one participant per unit was randomised to receive art at any time making it difficult to organise group sessions, therefore participants received fewer group sessions (2.5 ± 1.5) than one to one sessions (4.1 ± 1.9)

Outcomes

Data transformation was only used for two outcomes, The Stroke Impact Scale Emotion and Communication scales at T3, which were skewed towards lower scores. These were transformed by squaring (score**2). All others were close to normal distribution.

Groups were well matched in terms of baseline characteristics and T1 scores on the outcomes of interest (table 3). 97% of participants completed all items on outcome measures at baseline, except for the Adult Dispositional Hope Scale, where full completion was only 86.5% and Recovery Locus of Control Scale where full completion was 77%. Participants reported these measures as difficult to understand and too long.

Change, between group difference and effect sizes

Examination of effects was not the purpose of this study and, data is presented here to illustrate change in each measure for the purpose of outcome selection for a definitive trial. For the selected Stroke Impact Scale subscales, participants completing the intervention had higher change scores (Mean, Standard Deviation) than the control group between T1 and T2 in Social Participation (3.4 ± 27.7 vs -2.7 ± 34.0), Emotion (5.8 ± 23.9 vs 5.3 ± 18.5) and Hand Function (26.7 ± 31.9 vs 25.7 ± 35.2) (table 4). However, differences were small and variability was high. For communication, change was negative between T1 and T2, with greatest decline in the intervention group (-10.1 ± 24.9 vs -1.4 ± 17.2). For

secondary outcomes, the intervention group had greatest improvement in Positive Affect (5.4±9.2 vs 1.7±9.9), lower increase in Negative Affect (3.2±10.8 vs 4.5±9.4) (table 4), and most improvement in self-efficacy for art (5.4±9.2 vs 1.79±9.9). For all other measures change was small and fairly equitable between groups (table 4). Mean between group differences at T2 reflected the pattern for change scores. For self-efficacy for art (mean difference = 2.6; 95% CI = 1.1 to 4.2; Cohen's d =0.35) mean difference favoured the intervention group; and for self-esteem (mean difference = 4.3; 95% CI = -7.3 to -1.3, Cohen's d = -0.51) and communication (mean difference = 6.4; 95% CI = -14.5 to 3.2; Cohen's d = -0.54) the mean difference favoured the control group (table 4).

Insert table 4 about here

For overall change T1 to T3 on the Stroke Impact Scale (table 5), the control group demonstrated most improvement on all domains except Emotion, where the change score was slightly greater for the intervention group (3.9±19.1 vs 3.5±20.8). Greater improvement for the intervention group for positive affect (4.3±7.5 vs 2.8±10.1) and lower increase in negative affect (3.3±11.0 vs 5.2±9.8) was maintained for overall change. The intervention group demonstrated greatest overall change in self-efficacy for art (2.1±4.1 vs 0.4±3.9), otherwise change in both groups was small and similar across the groups (table 5).

Insert table 5 about here

In terms of estimated mean differences at T3, the pattern was similar to T2, favouring the intervention group for hand function, social participation, positive and negative affect and self-efficacy for art (table 5). Although small to moderate, effect size favoured self-efficacy for art in the intervention group (mean difference =2.1; 95% CI = 0.4 to 3.8; Cohen's d = 3.0) and the general self-efficacy significantly in the control group (mean difference = 3.0;

95%CI =-5.9 to -0.2; Cohen's d = -0.28). Other outcomes showed very small effect sizes, most favouring the control group.

Discussion

Findings show that conducting a definitive RCT to test a visual arts intervention within stroke rehabilitation is feasible. Recruitment and retention were comparable to other stroke rehabilitation trials^{40,41}, however preference for art may have influenced study retention. The study was not designed to definitively evaluate effectiveness however data analysis indicated that expected improvements in the nominated primary outcome were not realised, but that positive affect and self-efficacy for art, may be improved. Findings suggest that the primary outcome should be changed for a definitive RCT.

Recruitment and retention

29% of potentially eligible participants were recruited, however 41% declined to provide consent for participation. Others were not included for clinical reasons. We did not have ethical approval to collect sociodemographic or clinical data from those declining to participate, so it is not clear if their characteristics differed clinically from those consenting to participate. However most declined because they had little interest in art participation. This ambivalence could be addressed by provision of taster sessions, allowing people to try art participation before consenting to trial participation and randomisation. Given earlier qualitative research conducted by this team, suggesting that people were surprised about what they could achieve in terms of art participation, such exposure may enhance recruitment rates.

The 20% withdrawal rate at T2 (n=8/41) was similar to that in other studies of psychological interventions⁴¹. Baseline scores were high for those dropping out and most of those dropping out were also ambivalent about art participation, possibly perceiving

little need to participate. Together these findings indicate incorporating preference into trial design may enhance recruitment and retention, and facilitate evaluation of the impact of preference for art participation on outcomes⁴².

Completion rates on some measures were low. The test battery was long and considered repetitive. A full trial should include fewer measures, examining only salient outcomes highlighted by this study.

Group participation

Difficulty running groups limited opportunities for interaction between survivors. Despite this, change in Social Participation was greater for the intervention group, suggesting as reported elsewhere, that art participation may enhance well-being via social interaction ^{14,17,43-45}. A definitive trial, randomising by clusters would ensure sufficient participants at individual sites to conduct group sessions. This design could facilitate evaluation of effects of group and individual sessions, and more robustly evaluate impact on social participation.

Change in Outcomes

Data was normally distributed in all outcomes except in two domains of the Stroke Impact Scale at T3, suggesting that there was unlikely to be recruitment bias in the sample in terms of outcomes of interest¹⁸. The study only provided indications of magnitude and direction of change and was not a definitive effectiveness study. Between-group differences were small and variability high, however change in positive and negative affect favoured the intervention indicating art participation may positively influence emotions.

The RCT of art participation with stroke survivors in Thailand¹⁶ showed improved depression and quality of life compared to controls receiving physiotherapy only. That there was no indication of effects on the selected quality of life measure using a similar art participation activity probably reflects low study power, or differences in concepts evaluated by the measures. The difference may also indicate that activities such as singing and meditation in addition to art participation, are indeed necessary for effectiveness. The present intervention involved choice and development of personally meaningful artwork, but activities in the other study were more prescribed and pre-determined, making direct comparison to this study difficult.

One study aim was to determine if the identified outcomes were relevant. The Positive and Negative Affect Scale reflected the selected definition of wellbeing and the positive emotional changes art participation was anticipated would confer. This contrasts with measures reflecting the absence of negative emotions such as anxiety and depression, as examined in the Thai study. Insensitivity of Positive and Negative Affect Scale to change in lower emotional arousal states⁴⁶ may explain why effect size in the present study was not larger, but probably also reflects the small sample size in this feasibility study. Potential intervention effects may have been missed by not measuring other less transient psychological consequences of stroke including anxiety and depression. Despite these limitations, both studies indicate art may positively influence emotional consequences of stroke. A future definitive RCT should include Positive and Negative Affect Scale as the primary outcome, probably with measures of anxiety and depression as secondary outcomes to capture these effects.

Stroke Impact Scale domains representing aspects of quality of life were influenced less by the art intervention than anticipated. Survivor perceived communication worsened over time, particularly in the intervention group. It is unlikely however that the

intervention caused poorer communication. Baseline clinical assessment of communication was not undertaken so there is no reliable estimate of actual rather than perceived communication. It is nonetheless probable that the intervention group experienced initial communication that became more apparent to them over time. Whilst art sessions were designed to support conversation, compared to formal approaches to conversation facilitation⁴⁷, communication was unstructured and incidental and thus likely to be insufficient to promote change. Communication should not be an outcome within a full-scale trial. Other SIS domains may have not been sufficiently sensitive to detect small changes conferred by art participation, and should not be included as an outcome in a future definitive trial.

General self-efficacy, self-esteem and hope have been associated with better stroke recovery ^{48,49}. There was no indication that art participation may influence these outcomes. High variability in scores and limited sensitivity to change in the measures may explain findings. However previous qualitative findings may have been over-interpreted, and these outcomes may not be relevant to this intervention.

As expected, self-efficacy for art was higher in the intervention group at T2 and T3, and, as predicted by Bandura's Social Cognitive Theory⁴¹, illustrates confidence and mastery through specific skills development. Self-efficacy for broader life activities was another key benefit identified in qualitative art participation studies ^{12,14,17}. There was no indication that art participation might influence general self-efficacy, suggesting, as predicted by Bandura, that self-efficacy is specific to mastery of particular activities. The earlier qualitative studies involved longer programmes of community based art participation than this study^{12,14}. Potential effects may not have been realised in the short timescale of the present study, and within the narrower social confines of the hospital environment.

514

515 ***Limitations***

516 Although psychotropic drug use at baseline was recorded baseline levels of depression
517 were not assessed to examine if those with initial depression improved more. A future
518 trial should include this evaluation, to determine participants most likely to benefit.
519 Furthermore, the control group received an art portfolio because usual practice on those
520 units was to have artwork available from previous art programmes. The portfolio was
521 assumed to be an inert intervention, to maintain study continued participation. However,
522 it may have provided some confounding effects. A future trial should include usual
523 intervention controls only. Group dynamics were not assessed, nor were effects of art on
524 sense of identity, which may clarify intervention mechanisms of action. These should be
525 included in a definitive trial.

526

527 **Conclusion**

528 Delivering and testing an art intervention in stroke rehabilitation was feasible. Art
529 participation is a complex intervention that *may* enhance aspects of wellbeing after
530 stroke, as defined by Kirkevold⁷. Positive affect and self-efficacy for art appeared to be
531 enhanced in this feasibility study however study adjustments would be important for a
532 definitive trial. These include a more targeted test battery with change of primary
533 outcome to affect, and detailed screening to ensure participants are interested enough in
534 art participation and complete the intervention. A cluster or stepped wedge design with
535 site level randomisation would guarantee group sessions. Given the intervention may
536 improve positive affect, it could be enhanced to specifically target improvement in this
537 domain, and should be the primary outcome for a future study. Whilst retaining the
538 primary purpose of a creative experience with artists, elements of art therapy,
539 particularly techniques known to be effective at improving positive emotions could be
540 included.

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- 681

table 1. Intervention Stages	Details
1. <i>Define initial creative goals.</i>	Artist meets participant to elicit information about their health and stroke-related impairments, to discuss interests and preferences
2. <i>Introduction to materials and mark making</i>	Ability to handle art materials ascertained during introductory work with materials. [drawing/collage/printing/painting/mixed-media techniques].
3. <i>From materials and mark making to developing personal project ideas and goals.</i>	Content or subjects of personal interest considered.
4. <i>Developing personal project ideas into creative finished pieces.</i>	Expression of content and creative interpretation facilitated by the artist.
5. <i>Review of completed work, mounting and display of work, celebration and future plans</i>	Completed creative piece of work as tangible output; further ideas progressed by repetition of intervention stages, facilitated by the artist

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table 2. Participant characteristics

Baseline Characteristics	Intervention Group (n= 41)	Control Group (n= 40)	
Days admission to randomisation (mean, SD)	11.2(7.6)	12.4(9.5)	685
Age (years) (mean, SD)	77.0(9.1)	75.6(8.8)	
Male, n (%)	19(46%)	17(42%)	686
Female, n (%)	22(54%)	23(58%)	
Ischaemic stroke, n (%)	36(88%)	35(87%)	687
Haemorrhagic stroke, n (%)	5(12%)	5(13%)	
Edinburgh Handedness Inventory, n (%)			
Left Handed	3(7)	6(15)	
Ambidextrous	2(5)	1(2.5)	
Right handed	36(88)	33(82)	
Side of hemiplegia, n (%)			
Left hemiplegia	22(54%)	23(57%)	689
Right hemiplegia	19(46%)	16(43%)	
NIH Stroke Scale (max=15) (mean, SD)	5.4(3.3)	5.2(3.7)	
Montreal Cognitive Assessment (max=30) (mean, SD)	18.4(5.4)	18.4(6.6)	690
Barthel Index (Max=100)	46.2(24.7)	46.0(26.8)	691
On Psychotropic Drugs n (%)	2(5%)	1(2.5%)	
Intervention Sessions (Max=8) (mean, SD)	5.6(2.6)	-	692
Preference for Art, n (%)			
View	9(22)	9(23)	
Participate	18(44)	15(37)	
None	14(34)	16(40)	693
Experience of Art, n (%)			
None	22(54)	27(67)	
A little	17(41)	12(30)	
A lot	2(5)	1(3)	694

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1 table 3. Baseline T1 scores on outcome measures, Mean, SD: Intervention Group, Control Group, dropouts at T2 assessment.
2

Outcome Measures	T1 score (mean, SD)		Participants who withdrew	
	Intervention Group (n= 41)	Control Group (n=40)	Intervention Group (n= 8)	Control Group (n=2)
Stroke Impact Scale (Min=0, Max=100)				
Emotion	69.6(19.5)	72.4(20.4)	87.6(9.5)	77.8(31.4)
Communication	75.5(21.6)	69.5(24.9)	73.2(16.1)	32.1(5.0)
Hand Function	16.1(27.3)	17.1(26.8)	52.0(30.3)	30.0 (0.0)
Social Participation	37.0(26.5)	39.5(26.3)	54.7(25.8)	18.7(0.0)
Positive and Negative Affect Schedule (min=0, max=50)				
Positive Affect (higher score better)	23.5(8.2)	24.3(7.8)	27.9 (7.1)	27.5 (2.1)
Negative Affect (lower score better)	20.2(7.8)	20.4 (8.1)	13.0(2.9)	15.5 (7.8)
Visual Analogue Self-Esteem Score (min=0, max=50)	37.6(7.6)	37.4(8.5)	43.9(3.9)	40.0 (12.7)
Adult Dispositional Hope Scale (min=8, max=64)	25.9(3.0)	26.4(3.7)	26.9(2.6)	25.0(7.1)
General Self-efficacy Scale (min=10, max=40)	31.4(5.0)	32.5(4.3)	32.1(5.4)	27.0(7.1)
Self-efficacy for Art (min=2, max=14)	6.7(3.5)	6.1(3.6)	4.7(2.6)	6.0(2.8)
Recovery Locus of Control Scale (min=9, max=45)	36.4(5.1)	35.5(6.4)	38.8(2.68)	34.0 (0.0)
Preference for ART Participation (n)				
No preference			3	1
Preference not met			3	1
Preference met			2	-

1 table 4. Mean (SD) Change scores T1 to T2; estimated between group differences and effect size estimation at T2

Outcome Measures	Change T1 to T2 (mean, SD)		Estimated Between Group Difference at T2		Standardised Effect Size Cohen's d (positive value favours Intervention)	
	Intervention Group (n= 33)	Control Group (n=38)	Estimated mean difference T2	95% Confidence Interval		
Stroke Impact Scale (Min=0, Max=100)						5
Emotion	5.8(23.9)	5.3(18.5)	2.8	-11.3 to 5.7	-0.35	
Communication	-10.1(24.9)	-1.4 (17.2)	6.4	-14.5 to 3.2	-0.54	
Hand Function	26.7(31.9)	25.7(35.2)	0.5	-14.4 to 13.4	-0.05	6
Social Participation	3.4(27.7)	-2.7(34.0)	0.1	-10.5 to 10.8	0.01	
						7
Positive and Negative Affect Schedule (min=0, max=50)						
Positive Affect (higher score better)	5.4(9.2)	1.7(9.9)	1.6	-2.2 to 5.3	0.24	8
Negative Affect (lower score better)	3.2(10.8)	4.5(9.4)	3.0	-0.7 to 6.7	0.42	
						9
Visual Analogue Self-Esteem Score (min=0, max=50)	-0.4 (6.7)	2.1(8.4)	4.3	-7.3 to -1.3	-0.51	
Adult Dispositional Hope Scale (min=8, max=64)	-0.9(3.5)	1.5(4.9)	0.8	-3.2 to 1.5	-0.12	10
General Self-Efficacy Scale (min=10, max=40)	-2.6(7.1)	1.5(6.6)	2.5	-5.8 to 0.7	-0.28	11
Self-efficacy for Art (min=2, max=14)	1.4(4.1)	0.4(3.7)	2.6	1.12 to 4.2	0.35	12
Recovery Locus of Control Scale (min=9, max=45)	1.3(6.7)	1.2(6.6)	0.4	-3.22 to 2.4	0.06	13

14 SD denotes standard deviation

1 table 5. Mean (SD) Change scores T1 to T2; estimated between group differences and effect size estimation at T2

Outcome Measures	Change T1 to T3 (mean, SD)		Estimated Between Group Difference at T3		Standardised Effect Size Cohen's d (positive value favours intervention)
	Intervention Group (n= 33)	Control Group (n=38)	Estimated Mean Difference T3	95% Confidence Interval	
Stroke Impact Scale (Min=0, Max=100)					
Emotion	3.9 (19.1)	3.5(20.8)	2.3	-10.3 to 5.8	-0.18
Communication	1.1 (21.8)	9.3(21.8)	4.4	-13.9 to 5.2	-0.11
Hand Function	29.8 (31.3)	34.5(41.3)	2.2	-20.5 to 15.7	-0.12
Social Participation	18.3 (30.3)	19.5(33.9)	5.2	-18.8 to 8.3	-0.17
Positive and Negative Affect Schedule (min=0, max=50)					
Positive Affect (higher score better)	4.3(7.5)	2.8(10.1)	0.5	-4.5 to 3.4	0.07
Negative Affect (lower score better)	3.3(11.0)	5.2 (9.8)	3.0	-0.4 to 6.4	0.18
Visual Analogue Self-Esteem Score (min=0, max=50)					
	-0.3(6.6)	-0.2(7.5)	1.9	-5.1 to 1.2	-0.06
Adult Dispositional Hope Scale (min=8, max=64)					
	-0.7(3.8)	-1.7(5.1)	0.4	-2.5 to 1.7	-0.06
General Self-efficacy Scale (min=10, max=40)					
	-2.0(6.4)	-0.7(6.5)	3.0	-5.9 to -0.2	-0.28
Self-efficacy for Art (min=2, max=14)					
	2.1(4.1)	0.4(3.9)	2.1	0.4 to 3.8	0.30
Recovery Locus of Control Scale (min=9, max=45)					
	0.7(7.7)	1.3(7.9)	0.7	-2.4 to 3.7	-0.09

14

15 SD denotes standard deviation

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1 Figure Caption: figure 1: Flow of Participants through the study

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5 **Declaration of Interest Statement**

6 The authors report no conflicts of interest.

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